

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK**

ROBERT STRINI et al.,

Plaintiffs,

v.

No. 05-CV-440
(GLS/DRH)

EDWARDS LIFESCIENCES CORPORATION
et al.,

Defendants.

**DAVID R. HOMER
U.S. MAGISTRATE JUDGE**

ORDER

In April 2001, plaintiff Robert Strini ("Strini") underwent heart surgery for the insertion of a Carpentier-Edwards Pericardial Bioprosthetic Heart Valve ("valve") manufactured by defendant Edwards Lifesciences Corporation ("Edwards"). Defs. Letter-Brief (Docket No. 54) at 1. The valve malfunctioned and was removed in August 2001 at which time it was discovered that the valve was infected with a mycobacterial organism. Id. Strini and his wife commenced this action in 2005 seeking recovery of damages in four causes of action alleging negligence, strict products liability, breach of warranty, and loss of consortium. Docket No. 1. On May 25, 2006, Strini served Edwards with a Second Demand for Production of Documents. Pl. Letter-Brief (Docket No. 56) at 1. Demand No. 21 sought production of documents describing the chemical formulae for the sterilization process utilized for the valve. Id.; Defs. Letter-Brief at 2. Edwards objected to the demand on the ground that all such formulae are irrelevant to any matter at issue in this case and has now moved to preclude discovery of those formulae. Docket Nos. 54, 59. Strini opposes the request and seeks an order compelling Edwards to produce the formulae. Docket Nos. 56,

62. For the reasons which follow, Edwards' motion is denied and Strini's motion for a compulsion order is granted.

Edwards contends first that two of Strini's four causes of action are preempted by the 1976 Medical Device Amendments to the 1938 Food, Drug and Cosmetic Act, 21 U.S.C. § 351 et seq. In this regard, Edwards contends that because the formulae were subjected to the rigorous testing and approval procedures required by this federal statute, Strini's state law claims for strict products liability and breach of warranty are preempted. Defs. Letter-Brief at 3-4. Edward's preemption argument may well prevail but is misplaced in this context. Strini's four causes of action remain in this case and Edwards' answer to those claims, Docket No. 23, leaves all four in dispute pending motions for summary judgment. Therefore, Edwards' motion on the ground that two claims will hereafter be found preempted affords no basis at this stage to preclude production of the formulae.

Even assuming preemption of two claims, however, Strini's claim for negligent manufacture and distribution is not subject to preemption, as Edwards concedes. Defs. Mem. of Law at 7. As to that claim alone, Strini seeks discovery of the formulae to evaluate whether Edwards processed his valve in accordance with the formulae. Contrary to Edwards' misconstruction of Strini's claim of relevance, Strini does not seek the formulae to challenge the adequacy, viability, or sufficiency of the formulae but to challenge Edwards' compliance with that formulae. Compliance cannot be evaluated without knowledge of the governing formulae. Those formulae likely constitute at least some evidence defining the standard of care which Strini contends Edwards breached in sterilizing the valve. This suffices to satisfy the broad standard for relevance set forth in Fed. R. Civ. P. 26(b)(1).


Finally, Edwards contends that no adequate protection exists for the formulae, which

constitute trade secrets. However, the parties previously stipulated to the entry of a confidentiality order protecting discovery of information such as the formulae. Docket No. 38. There has been no showing as to why the provisions of that order will not suffice to provide adequate protection for the formulae as they have for all other information provided during discovery in this case.

WHEREFORE, it is hereby

ORDERED that Edwards' motion to preclude discovery of the formulae demanded in Strini's Document Demand No. 21 (Docket No. 54) is **DENIED**, Strini's motion for an order compelling Edwards to produce the formulae demanded in his Document Demand No. 21 (Docket No. 56) is **GRANTED**, and Edwards shall serve Strini with a response to Document Demand No. 21 regarding the formulae on or before **December 8, 2006**.

IT IS SO ORDERED.



United States Magistrate Judge

DATED: November 28, 2006
Albany, New York